

## Midazolam Injection

### DEFINITION

Midazolam Injection is a sterile solution of Midazolam Hydrochloride in Water for Injection or of Midazolam in Water for Injection prepared with the aid of Hydrochloric Acid. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of midazolam ( $C_{18}H_{13}ClFN_3$ ). It may contain Sodium Chloride, Benzyl Alcohol, and/or a chelating agent.

### IDENTIFICATION

- The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

### ASSAY

[NOTE—Protect all prepared Standard and sample solutions from light.]

#### • PROCEDURE

**Buffer:** 6.7 g/L of dibasic sodium phosphate heptahydrate in water. Adjust with phosphoric acid to a pH of  $5.0 \pm 0.1$ .

**Solution A:** Prepare a filtered and degassed mixture of acetonitrile, methanol and *Buffer* (8:3:9).

**Solution B:** Acetonitrile and *Buffer* (3:1)

**Mobile phase:** See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	100	0
20	0	100
35	0	100
37	100	0
45	100	0

**Standard solution:** Dissolve USP Midazolam RS in about 2 mL of methanol, and dilute quantitatively, and stepwise if necessary, with *Solution A* to obtain a 0.2-mg/mL solution.

**Sample solution:** [NOTE—The midazolam present in the Injection converts from the open-ring form to the closed-ring form when diluted